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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/647,495 | 08/25/2003 | Bertram N. Ezenwa | 282.037 | 2371 |
| 7590 | 06/15/2006 | | EXAMINER | |
| William T. Kryger BOYLE, FREDRICKSON, NEWHOLM, STEIN & GRATZ S.C. Suite 1030 250 E. Wisconsin Avenue Milwaukee, WI 53202 | | | APANIUS, MICHAEL | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |
| DATE MAILED: 06/15/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/647,495 | EZENWA, BERTRAM N. ✓ | |
| | Examiner | Art Unit | |
| | Michael Apanius | 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 March 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3,5,8-16,18-22,25 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3,5,8-16,18-22,25 and 27-30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 March 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the amendment filed 3/27/2006. The Examiner acknowledges the amendments to claims 1, 5, 8, 14, 15, 25 and 27; the cancellation of claims 4, 6, 7, 17, 23, 24 and 26; 4 replacement drawing sheets; and amendments to the specification. Currently, claims 1-3, 5, 8-16, 18-22, 25 and 27-30 are pending.

Drawings

2. The replacement drawings are accepted.

Specification

3. The disclosure is objected to because of the following informalities: at page 8, line 19, it appears that "excitation" should be --sensing--. Appropriate correction is required.

Claim Objections

4. Claims 1-3, 5, 8-14 and 16 are objected to because of the following informalities. At claim 1, line 14, it appears that --ratio-- should be inserted after "pressure normalization". At claim 16, line 2, it appears that "against" should be --engages--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 5, 9 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 5, 9 and 18 are indefinite because they depend from cancelled claims.

7. Claims 25, 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: normalizing the signal received by the sensing electrode in response to the pressure normalization ratio. Without this step, it is unclear how determining the pressure normalization ratio relates to the rest of the claim and, therefore, the scope of the claim is indefinite.

8. Claims 1-3, 5 and 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted functional element is: normalizing the acquired signal from the sensing electrode based on the pressure normalization ratio. Without this limitation, it is unclear how determining the pressure normalization ratio relates to the rest of the claim and, therefore, the scope of the claim is indefinite.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eifler (DE 197 15 421).

11. In regards to claim 1, Eifler discloses an apparatus capable of sensing the amplitude of a signal traveling through a body that is generated by an excitation device, comprising: a sensing electrode (9) operatively engagable with the body under a pressure downstream of the excitation device for sensing a signal generated by an excitation device; a pressure mounting structure (1) operatively connected to the sensing electrode for controlling the pressure at which the sensing electrode engages the body; a pressure sensor (11-15) disposed adjacent the sensing electrodes; and a controller (data processing device in abstract). Note that changing the force with which the pressure mounting structure is held against the skin controls the pressure. In regards to claim 8, Eifler discloses correcting an acquired signal from the sensing electrode. In regards to claim 9, Eifler discloses displaying values and therefore, the controller is also capable of displaying a pressure value. However, Eifler does not expressly disclose (in the English abstract) a controller that determines a pressure normalization ratio and uses the ratio to normalize the acquired signal.

12. Eifler teaches generating a pressure signal and using the pressure signal to correct electrical signals recorded at an electrode for the purpose of providing improved accuracy of the electrical measurements (see English abstract). Although Eifler does not expressly teach a pressure normalization ratio in the abstract, the steps of determining a pressure normalization ratio and using it to correct an electrical signal are an obvious implementation of the signal correction disclosed by Eifler. For example, it would have been obvious to one having ordinary skill in the art to have calculated a value, or ratio, from the pressure signal and then to have multiplied the measured electrical signal with the calculated value to normalize the electrical signal. This simple implementation is clearly well known in the art and meets the language used in the claims.

13. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to determine a pressure normalization ratio and to normalize the signal from the electrode using the ratio in the apparatus Eifler because it is a simple correction algorithm that is well-known in the art.

14. Claims 1, 2, 5, 8, 15, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho (US 6,174,290) in view of Eifler (DE 197 15 421).

15. In regards to claims 1, 15 and 20, Cho discloses an apparatus that is capable of sensing the amplitude of a signal generated by an excitation device operatively engaging the body, comprising: a sensing electrode (3) operatively engagable with the body under a pressure that is capable of being placed downstream from an excitation

device to sense a signal generated by an excitation device; and a pressure mounting structure (1) operatively connected to the sensing electrode for controlling the pressure at which the sensing electrode engages the body. The apparatus further comprises a pressure sensor (5) disposed adjacent the sensing electrode. The apparatus further comprises a controller (figure 3) electrically connected to the pressure sensor for receiving the pressure signal and to the sensing electrode for receiving the signal sensed by the sensing electrode. In regards to claims 2 and 15, the pressure mounting structure includes a pressure source (4) operatively connected to the sensing electrode for applying the pressure at which the sensing electrode engages the body. In regards to claims 5 and 18, the pressure sensor is a load cell (column 5, line 18). However, Cho does not expressly disclose a controller that determines a pressure normalization ratio and normalizes the signal from the electrode.

16. Eifler teaches using a pressure sensor and controller to correct electrical signals recorded at an electrode for the purpose of providing improved accuracy of the electrical measurements (see English abstract). Although Eifler does not expressly teach a pressure normalization ratio in the abstract, the steps of determining a pressure normalization ratio and using it to correct an electrical signal are an obvious implementation of the signal correction disclosed by Eifler. For example, it would have been obvious to one having ordinary skill in the art to have calculated a value, or ratio, from the pressure signal and then to have multiplied the measured electrical signal with the calculated value to normalize the electrical signal. This simple implementation is clearly well known in the art and meets the language used in the claims.

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17. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a signal generated by the pressure sensor and a controller to determine a pressure normalization ratio and to normalize the signal from the electrode, as taught by Eifler and as is well-known in the art, in the apparatus of Cho in order to improve the accuracy of the electrical measurements.

18. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cho (US 6,174,290) as modified by Eifler (DE 197 15 421) as applied to claims 1, 2, 5, 8, 15, 18 and 20 above, and further in view of Heilbrun et al. (US 5,389,101).

19. Cho as modified by Eifler discloses the limitations of claim 15 as noted above. However, Cho as modified by Eifler does not expressly disclose a light source.

20. Heilbrun teaches a light source (column 10, lines 7-11) configured to illuminate a grid on the body for the purpose of creating a workspace coordinate framework for defining the location of a medical instrument relative to a body region (column 3, lines 6-10).

21. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a light source in the apparatus of Cho as modified by Eifler as taught by Heilbrun in order to create a workspace coordinate framework.

22. Claims 1, 8, 10, 11, 25 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemmen (US 5,327,902) in view of Eifler (DE 197 15 421).

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23. In regards to claim 1, Lemmen discloses an apparatus for sensing the amplitude of a signal traveling through a body that is generated by an excitation device, comprising: a sensing electrode (10) operatively engagable with the body under a pressure downstream of the excitation device for sensing a signal generated by an excitation device; and a pressure mounting structure (30) operatively connected to the sensing electrode for controlling the pressure at which the sensing electrode engages the body. Note that changing the force with which the pressure mounting structure is held against the skin controls the pressure. In regards to claim 10, the apparatus has a positioning structure (50) operatively connected to the sensing electrode for positioning the sensing electrode at a user selected location adjacent the body. In regards to claim 11, the positioning structure is a vertical positioning device which allows a user to adjust the vertical position of the sensing electrode relative to the body when the arm is held straight up. However, Lemmen does not expressly disclose a pressure sensor or a controller that determines a pressure normalization ratio and normalizes the signal from the electrode.

24. In regards to claim 25, Lemmen discloses a method for sensing a signal traveling through a body, the signal generated by an excitation device operatively engaging the body, the method comprising the steps of: positioning a sensing electrode on the body (column 5, lines 30-33); exerting a pressure on the sensing electrode against the body (column 5, lines 30-33); and receiving the signal with the sensing electrode (column 5, lines 37-39). In regards to claim 28, the pressure exerted on the sensing electrode is normal to the body. In regards to claim 29, the amplitude level of the signal is

measured (column 5, lines 37-42). In regards to claim 30, the above steps are repeated (column 5, lines 39-42). However, Lemmen does not expressly disclose generating a pressure signal, determining a pressure normalization ratio or normalizing the signal.

25. Eifler teaches generating a pressure signal and using the pressure signal to correct electrical signals recorded at an electrode for the purpose of providing improved accuracy of the electrical measurements (see English abstract). Although Eifler does not expressly teach a pressure normalization ratio in the abstract, the steps of determining a pressure normalization ratio and using it to correct an electrical signal are an obvious implementation of the signal correction disclosed by Eifler. For example, it would have been obvious to one having ordinary skill in the art to have calculated a value, or ratio, from the pressure signal and then to have multiplied the measured electrical signal with the calculated value to normalize the electrical signal. This simple implementation is clearly well known in the art and meets the language used in the claims.

26. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to used a pressure sensor and controller to generate a pressure signal, to determine a pressure normalization ratio, and to normalize the signal from the electrode, as taught by Eifler and as is well-known in the art, in the apparatus and method of Lemmen in order to improve the accuracy of the electrical measurements.

27. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lemmen (US 6,174,290) as modified by Eifler (DE 197 15 421) as applied to claims 1, 8, 10, 11, 25 and 27-30 above, and further in view of Heilbrun et al. (US 5,389,101).
28. Lemmen as modified by Eifler discloses the limitations of claim 10 as noted above. However, Lemmen as modified by Eifler does not expressly disclose a light source.
29. Heilbrun teaches a light source (column 10, lines 7-11) configured to illuminate a grid on the body for the purpose of creating a workspace coordinate framework for defining the location of a medical instrument relative to a body region (column 3, lines 6-10).
30. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a light source in the apparatus of Lemmen as modified by Eifler as taught by Heilbrun in order to create a workspace coordinate framework.
31. Claims 1-3, 8, 14-16 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (US 5,485,848) in view of Inukai et al. (US 5,865,761) and Eifler (DE 197 15 421).
32. In regards to claims 1, 15 and 20, Jackson discloses an apparatus comprising: a pressure mounting structure (figure 4, 86) for controlling the pressure at which the apparatus engages the body. The apparatus further comprises a pressure sensor (110). In regards to claims 2 and 15, the pressure mounting structure includes a

pressure source (102; paragraph bridging column 6 and column 7). In regards to claims 3, 16 and 22, the pressure source is a micrometer configured to adjust the pressure at which the apparatus engages the body. In regards to claims 14 and 21, the pressure mounting structure is a strap operatively connected to the pressure sensor. However, Jackson does not expressly disclose a sensing electrode or a controller that determines a pressure normalization ratio and normalizes the signal from the electrode.

33. Inukai teaches a sensing electrode (90) combined with a strap-like blood pressure measuring device for the purpose of allowing multiple simultaneous measurements to be made in a single set-up (column 1, lines 56-62). The sensing electrode of Inukai is capable of sensing a signal traveling through the body that was generated by an excitation device.

34. Eifler teaches using a pressure sensor and controller to correct electrical signals recorded at an electrode for the purpose of providing improved accuracy of the electrical measurements (see English abstract). Although Eifler does not expressly teach a pressure normalization ratio in the abstract, the steps of determining a pressure normalization ratio and using it to correct an electrical signal are an obvious implementation of the signal correction disclosed by Eifler. For example, it would have been obvious to one having ordinary skill in the art to have calculated a value, or ratio, from the pressure signal and then to have multiplied the measured electrical signal with the calculated value to normalize the electrical signal. This simple implementation is clearly well known in the art and meets the language used in the claims.

35. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have added a sensing electrode to the apparatus of Jackson as taught by Inukai in order to make multiple simultaneous measurements in a single set-up.

36. Furthermore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a signal generated by the pressure sensor and a controller to determine a pressure normalization ratio and to normalize the signal from the electrode, as taught by Eifler and as is well-known in the art, in the apparatus of Jackson as modified by Inukai in order to improve the accuracy of the electrical measurements.

37. Claims 1, 2, 10, 12, 15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walters (US 3,067,749) in view of Eifler (DE 197 15 421).

38. In regards to claims 1, 15 and 20, Walters discloses an apparatus that is capable of sensing the amplitude of a signal traveling through a body that is generated by an excitation device, comprising: a sensing electrode (20) operatively engagable with the body under a pressure that is capable of being placed downstream from an excitation device to sense a signal generated by an excitation device; and a pressure mounting structure (30) operatively connected to the sensing electrode for controlling the pressure at which the sensing electrode engages the body. In regards to claims 2 and 15, the pressure mounting structure includes a pressure source (50) operatively connected to the sensing electrode for applying the pressure at which the sensing electrode engages

the body. In regards to claim 10, the apparatus has a positioning structure (40, 42, 44) operatively connected to the sensing electrode for positioning the sensing electrode at a user selected location adjacent the body. In regards to claim 12, the positioning structure is a dial configured to rotate the sensing electrode about a horizontal axis so as to allow a user to control an angle at which the sensing electrode engages the body. However, Walters does not expressly disclose a pressure sensor or a controller that determines a pressure normalization ratio and normalizes the signal from the electrode.

39. Eifler teaches generating a pressure signal and using the pressure signal to correct electrical signals recorded at an electrode for the purpose of providing improved accuracy of the electrical measurements (see English abstract). Although Eifler does not expressly teach a pressure normalization ratio in the abstract, the steps of determining a pressure normalization ratio and using it to correct an electrical signal are an obvious implementation of the signal correction disclosed by Eifler. For example, it would have been obvious to one having ordinary skill in the art to have calculated a value, or ratio, from the pressure signal and then to have multiplied the measured electrical signal with the calculated value to normalize the electrical signal. This simple implementation is clearly well known in the art and meets the language used in the claims.

40. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to used a pressure sensor and controller to generate a pressure signal, to determine a pressure normalization ratio, and to normalize the signal from the

electrode, as taught by Eifler and as is well-known in the art, in the apparatus of Walters in order to improve the accuracy of the electrical measurements.

Response to Arguments

41. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8:30am-5pm.

43. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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44. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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